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Johnson & Johnson Pharmaceutical Research & Development, LLC

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ORTHO-McNEIL PHARMACEUTICAL, INC., *et al.* Plaintiffs, v. BARR LABORATORIES, INC., Defendant.	Civil Action No. 03-CV-4678 (SRC)

DECLARATION OF ERIC R. SONNENSCHEIN

I, Eric R. Sonnenschein, declare as follows:

1. I am an attorney for plaintiffs Ortho-McNeil Pharmaceutical, Inc. and

Johnson & Johnson Pharmaceutical Research and Development, LLC. I have personal knowledge of, and am competent to testify to, the matters set forth herein.

2. Attached as Exhibit A to this declaration is the declaration of Katherine Capperella, dated July 1, 2009.

3. Attached as Exhibit B to this declaration is the declaration of Patricia Lukens, dated July 1, 2009.

4. Attached as Exhibit C to this declaration is a true copy of a letter sent to counsel for Barr on June 30, 2009, seeking Barr's agreement not to launch its generic version of ORTHO TRI-CYCLEN LO until resolution of this matter, whether by settlement or trial on the merits. In that same letter, Ortho requested that Barr agree to provide 90 day notice prior to any launch, and to confirm that it would not launch its generic product prior to responding to Ortho's requests for an agreement.

5. Attached as Exhibit D to this declaration is a true copy of Barr's response to Ortho's letter, received on July 1. In that response, Barr advised Ortho that it had commenced shipment of its generic product.

6. Attached as Exhibit E to this declaration is Plaintiffs' Trial brief from this case.

7. Attached as Exhibit F to this declaration is the Expert Report of Rogerio Lobo, M.D., dated September 23, 2005 (as amended February 22, 2006).

8. Attached as Exhibit G to this declaration is the Plaintiffs' Trial Exhibit 51, U.S. Patent No. 4,616,006.

9. Attached as Exhibit H to this declaration is the Plaintiffs' Trial Exhibit 52, U.S. Patent No. 4,628,051.

10. Attached as Exhibit I to this declaration is the Plaintiffs' Trial Exhibit 63, U.S. Patent No. 6,214,815.

11. Attached as Exhibit J to this declaration is Plaintiffs' Trial Exhibit 143, Barr's Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act.

12. Attached as Exhibit K to this declaration is Plaintiffs' Trial Exhibit 141, Consent Order dated August 3, 2005, Civ. A. No. 03-CV-4678 (SRC).

13. Attached as Exhibit L to this declaration is the Plaintiffs' Trial Exhibit 83, Darney P.D. and Klaisle C.M., *Contraception-Associated Menstrual Problems: Etiology and Management*, Dialogues in Contraception 1998; 5:1-12.

14. Attached as Exhibit M to this declaration is the Plaintiffs' Trial Exhibit 86, Endrikat J. et al., *A Twelve-Month Comparative Clinical Investigation of Two Low-Dose Oral Contraceptives Containing 20 μg Ethinylestradiol/75 μg Gestodone and 30 μg Ethinylestradiol/75 μg Gestodene, with Respect to Efficacy, Cycle Control, and Tolerance*, Contraception 1997; 55(3): 131-137.

15. Attached as Exhibit N to this declaration is the Plaintiffs' Trial Exhibit 91, Hampton, R.M. et al., *Comparison of a Novel Norgestimate/Ethinyl Estradiol Oral Contraceptive (Ortho Tri-Cyclen Lo) With the Oral Contraceptive Loestrin Fe 1/20,* Contraception 2001; 63:289-295.

16. Attached as Exhibit O to this declaration is the Plaintiffs' Trial Exhibit 94, Kaunitz A.M., *Enhancing Oral Contraceptive Success: The Potential of New Formulations*, Am J Obstet and Gynecol 2004: 190:S23-29.

17. Attached as Exhibit P to this declaration is the Plaintiffs' Trial Exhibit 98, Kaunitz A.M., *Oral Contraceptive Estrogen Dose Considerations*, Contraception 1998; 58:15S-

21S.

18. Attached as Exhibit Q to this declaration is the Plaintiffs' Trial Exhibit 100, Lawson J. et al., *Optimum Dosage of an Oral Contraceptive: A report from the Study of Seven Combinations of Norgestimate and Ethinyl Estradiol*, Am J. Obstet Gynecol 1979; 134(3):315-320.

19. Attached as Exhibit R to this declaration is the Plaintiffs' Trial Exhibit 103, Lobo R. and Stanczyk F., *New knowledge in the physiology of hormonal contraceptives*, Am J Obstet Gynecol 1994; 170(5):1499-1507.

20. Attached as Exhibit S to this declaration is the Plaintiffs' Trial Exhibit 109, Mishell D.R., *Oral Contraception: Past, Present, and Future Perspectives*, Int'l J Fertil 1992 (Suppl. 1):7-37.

21. Attached as Exhibit T to this declaration is the Plaintiffs' Trial Exhibit 110, Mishell D.R. et al., *Bleeding Patterns with Hormonal Contraceptives and IUDS*, Dialogues in Contraception 2002; 7(6):2.

22. Attached as Exhibit U to this declaration is the Plaintiffs' Trial Exhibit 116, Petitti D.B. et al., *Oral Contraceptives, Smoking, and Other Factors in Relation to Risk of Venous Thromboembolic Disease*, Am J Epidemiol 1978; 108:480-485.

23. Attached as Exhibit V to this declaration is the Plaintiffs' Trial Exhibit 118, Rosenberg M.J. et al., *Efficacy, Cycle Control, and Side Effects of Low- and Lower-Dose Oral Contraceptives: A Randomized Trial of 20 μg and 35 μg Estrogen Preparations*, Contraception 1999; 60:321-329.

24. Attached as Exhibit W to this declaration is the Plaintiffs' Trial Exhibit 121, Royal College of General Practitioners, *Oral Contraceptive Study: Oral Contraceptives,*

Venous Thrombosis and Varicose Veins, J Roy Coll Gen Prac 1978 28:393-399.

25. Attached as Exhibit X to this declaration is the Plaintiffs' Trial Exhibit 134, Vessey M. et al., *Oral Contraceptives and Venous Thromboembolism: Findings in a Large Prospective Study*, Br. Med. J. 1986; 292:526.

26. Attached as Exhibit Y to this declaration is the Plaintiffs' Trial Exhibit 136, Williams, J.K., *Rationale for New Oral Contraceptive Dosing*, Intl J Fertil 2004; 49(1):30-35.

27. Attached as Exhibit Z to this declaration is the Plaintiffs' Trial Exhibit 140, *Defendant Barr Laboratories, Inc.'s Supplemental Responses to Certain of Plaintiffs' First Set of Interrogatories*, dated September 15, 2004, Civ. A. No. 03-CV-4678.

28. Attached as Exhibit AA to this declaration is the Plaintiffs' Trial Exhibit 145, Clinical Study Report, "A Randomized, Comparative, Multicenter, Safety, and Contraceptive Efficacy Study of Two Cyclophasic Norgestimate/Ethinyl Estradiol Regimens, and One Triphasic Norgestimate/Ethinyl Estradiol (RWJ-01403-000) Regimen (RWJ-10131-000) and Loestrin Fe 1/20 (Protocol NRGLOW-OC-001; Phase 3)"(OMP 019221 - OMP 019331; OMP 019876 - OMP 019950).

29. Attached as Exhibit BB to this declaration is the Plaintiffs' Trial Exhibit 156, Clinical Study Report, "A Double-Blind, Randomized, Phase II Study to Evaluate the Safety and Efficacy of Various Cyclophasic Regimens of Norgestimate and Ethinyl Estradiol with an Open-Label Ortho Tri-Cyclen Control, Protocol N93-031"(OMP 022921 - 022970; OMP 023006 - 023165).

30. Attached as Exhibit CC to this declaration is Plaintiffs' Trial Exhibit 157, Expert Report of Marion B. Stewart, Ph.D., dated September 22, 2005.

31. Attached as Exhibit DD to this declaration is Plaintiffs' Trial Exhibit 175, Expert Report of Diane S. Feldman, dated September 23, 2005.

32. Attached as Exhibit EE to this declaration is Plaintiffs' Trial Exhibit 178, Expert Report of Risa Kagan, M.D., dated September 22, 2005 (as corrected December 13, 2005).

33. Attached as Exhibit FF to this declaration is Plaintiffs' Trial Exhibit 194, Ortho-McNeil Marketing Contribution Statement re: ORTHO TRI-CYCLEN LO through 2006 (OMP-E-00864).

34. Attached as Exhibit GG to this declaration is Plaintiffs' Trial Exhibit 195, IMS Oral Contraceptive Sales and Marketing Data (2001-11/2006) (OMP-E-000864).

35. Attached as Exhibit HH to this declaration is Plaintiffs' Trial Exhibit 245, PTO Manual of Patent Examinig Procedure (7th Ed. 1988).

36. Attached as Exhibit II to this declaration is the Plaintiffs' Trial Exhibit 70, Akerlund M. et al., *Comparative Profiles of Reliability, Cycle control and Side Effects of Two Oral Contraceptive Formulations Containing 150 μg Desogestrel and Either 30 μg or 20 μg Ethinyl Oestradiol*, British Journal of Obstetrics 1993; 100: 832-838.

37. Attached as Exhibit JJ to this declaration is the Plaintiffs' Trial Exhibit 74, Bounds W et al., *A Randomized Double-Blind Trial of Two Low Dose Combined Oral Contraceptives*, British Journal of Obstetric and Gynaecology 1979; 86: 325-329.

38. Attached as Exhibit KK to this declaration is the Plaintiffs' Trial Exhibit 37, which is the Certified Patent Office File Wrapper for U.S. Letters Patent No. 6,214,815.

39. Attached as Exhibit LL to this declaration is the Plaintiffs' Trial Exhibit 49, U.S. Patent No. 4,530,839.

40. Attached as Exhibit MM to this declaration is Teva Pharmaceutical Industries Ltd. Press Release "Teva Announces Approval and Launch of Tri-Lo Sprintec Tablets", dated July 1, 2009.

41. Exhibits E-LL are true and correct copies of papers filed/submitted to the Court in this case.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief. Executed on July 1, 2009.

Eric R. Sonnenschein